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Pabst Patent Group LLP  
400 Colony Square, Suite 1200  
1201 Peachtree Street  
Atlanta, GA 30361Telephone (404) 879-2150  
Telefax (404) 879-2160information@pabstpatent.com  
www.pabstpatent.com

## TELEFAX

Date: June 27, 2005

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To: U.S. PTO

Telephone:

Telefax: 703-872-9306

From: Patrea L. Pabst

Telephone: 404-879-2151

Telefax: (404) 879-2160

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## MESSAGE:

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Abraham J. Domb and Joseph S. Wolnerman

Serial No.: 10/083,413

Art Unit: 1654

Filed: February 27, 2002

Examiner: Flood, Michele C.

For: *ABSORBABLE SOLID COMPOSITIONS FOR TOPICAL TREATMENT OF  
ORAL MUCOSAL DISORDERS*Attachments

Fee Transmittal Form PTO/SB/17

Transmittal Form PTO/SB/21

Appeal Brief

(45058186.1)

U.S.S.N. 10/083,413  
Filed: February 27, 2002  
APPEAL BRIEF

### Claims Appendix: Claims On Appeal

1. A solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising:

(a) a bioactive amount of at least one herbal active agent selected from the group consisting of bioactive herbs, herbal extracts, tinctures, essential oils, and mixtures thereof or an agent selected from the group consisting of analgesics, anti-inflammatories, antihistamines, antigens, steroids other than anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial, antiulcer drugs, peptides, and combinations thereof, wherein the agent is present in a homeopathic amount, which is less than a therapeutically effective amount; and

(b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa.

2. The solid composition of claim 1 wherein the composition is in the form of a disc of 2 to 15 mm diameter and 0.4 to 2.3 mm thick that adheres to the oral mucosal tissue for at least 30 minutes.

3. The solid composition of claim 1 where the composition is in the form of a disc 5 to 11 mm in diameter and 1 to 2 mm thick with tissues adherence of at least 1 hour.

4. The composition of claim 1 wherein the herbal active agent is selected from the group consisting of anti-inflammatory, analgesic, antiaching, anesthetic, antimicrobial, antifungal, antiseptic, antiviral, antibiotic, antiparasite agents, and combinations thereof.

5. (canceled)

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27

EBL 102  
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U.S.S.N. 10/083,413  
Filed: February 27, 2002  
APPEAL BRIEF

6. The composition of claim 1 wherein the herbal active agent or homeopathic agent is selected from the group consisting of Echinacea, *Salvia officinalis*, *Hypericum*, Myrrh, Camphoria, *Uncaria*, menthol, *Plantago*, *Baptisia*, *Calendula*, *Phytolacca*, Catechu black, Coneflower, *Krameria*, *Tsuga*, grape fruit seed extract, *Rosmarinus*, *Styrax*, *Crataegus*, *Glycyrrhiza*, *Angelica*, *Krameria*, *Matricaria*, Mallow, Propolis, Sage, berberine from *hydrastis canadensis* L., plant family Berberidaceae, gentian from the gentianaceae family of plants for the treatment of fungal infections, monoterpenes of three unsaturations, *Taraxacum* extract, *Lonicera* flower extract, *Scutellaria* root extract, *Gardenia* fruit extract, *Pulsatilla* root extract, *Pueraria* root extract, *Radix gentianae* Longdancao antifungal agent, and combinations thereof.

7. The composition of claim 1, wherein the herbal active agent is an essential oil selected from the group consisting of citronella oil, lemon oil, citron oil, pomelo peel oil, cedarwood oil, juniper berries oil, lemon basil oil, *Rosmarinus officinalis* oil, cinnamon oil, cajeput oil, eucalyptus oil, fennel oil, geranium oil, girofle oil, lavender oil, clove oil, spearmint oil, myrtle oil, oregano oil, pine oil, rosemary oil, sarriette oil, thyme oil, tea-tree oil, and combinations thereof.

8. The composition of claim 7, wherein the herbal active agent is an essential oil selected from the group consisting of cinnamon oil, tea-tree oil, citronella oil, and combinations thereof.

9. The composition of claim 6, wherein the herbal active agent comprises at least one monoterpene with three unsaturations.

10. The composition of claim 1, wherein the herbal active agent is an essential oil and the essential oil is a natural or synthetic mixture consisting of limonene and at least one myrcene,

U.S.S.N. 10/083,413  
Filed: February 27, 2002  
APPEAL BRIEF

a-pinene, b-pinene, and sabinene characterized in that at least 60% by weight of the mixture is limonene.

11. The composition of claim 9, wherein the monoterpene with three unsaturations is a citrus oil selected from the group consisting of lemon oil, pomelo oil, citron oil, and combinations thereof.

12. The composition of claim 1, further comprising a salt selected from the group consisting of  $MgBr_2$ , NaCl, KCl and mixtures thereof.

13. (canceled)

14. The composition of claim 1 further comprising Carnallite or a salt of Carnallite.

15. The composition of claim 1, further comprising a non-herbal active agent.

16. The composition of claim 15, wherein the agent is selected from the group consisting of at least one base or acid-addition salt of procaine, lidocaine, prilocaine, mepivacaine, dyclonine, dibucaine, benzocaine, chlorprocaine, tetracaine, bupivacaine, and etidocaine.

17. The composition of claim 15, wherein the non-herbal active agent is selected from the group consisting of at least one base or acid-addition salt of dexamethasone, triamcinolone, hydrocortisone, amphotericine B, nystatin, itraconazole, chlorhexidine, quaternary ammonium salts, parabens, and dextranase enzymes.

18. The composition of claim 14, wherein said Carnallite or a-salt of Carnallite improves the activity of the herbal active agents.

U.S.S.N. 10/083,413  
Filed: February 27, 2002  
APPEAL BRIEF

19. The composition of claim 1, wherein the active agent consists of a mixture of natural or synthetic monoterpenes with three unsaturations selected from the group consisting of limonene, myrcene, pinenes, sabinene, and terpinene.

20. The composition of claim 15 comprising a citron oil and Carnallite salt at a ratio between 1:10 and 1:1.

21. The composition of claim 15 comprising a citron oil and Carnallite salt at a ratio between 1:10 and 1:1 and a local anesthetic selected from the group consisting of lidocaine, benzocaine, and bupivacaine.

22. The composition of claim 1, wherein the solid bioadhesive carrier is selected from the group consisting of a natural, semisynthetic or synthetic polyhydric polymer, a polycarboxylic acid polymer and mixtures thereof.

23. The composition of claim 22 wherein the polyhydric polymer is selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethylcellulose, carboxymethyl cellulose, dextran, arabinogalactan, pullulan, guar-gum, hyaluronic acid, pectins, starch derivatives, acrylic acid polymers, polymer of acrylic acid esters, acrylic acid copolymers, polymers of vinyl alcohols, alkoxy polymers, polyethylene oxide polymers, polyethers and combinations thereof.

24. The composition of claim 1 further comprising an excipient selected from the group consisting of fillers, tableting excipients, lubricants, enhancers, flavors, taste-masking agents, pH controlling compounds, dyes, stabilizers, enzyme inhibitors, and mixtures thereof.

U.S.S.N. 10/083,413  
Filed: February 27, 2002  
**APPEAL BRIEF**

25. The composition of claim 24 wherein the enhancers are selected from the group consisting of bile acids and limonene.

26. The composition of claim 22 wherein the solid bioadhesive carrier is selected from polyacrylic acid polymers lightly crosslinked with a polymer selected from the group consisting of polyalkenyl polyether, carboxymethylcellulose, hydroxymethylcellulose, and mixtures thereof.

Claims 27-37. (canceled)

38. The composition of claim 1, wherein the composition has a surface area ranging from about 0.4 to about 3 cm<sup>2</sup>.

**TABLE OF CONTENTS**

- (1) REAL PARTY IN INTEREST**
- (2) RELATED APPEALS AND INTERFERENCES**
- (3) STATUS OF CLAIMS**
- (4) STATUS OF AMENDMENTS**
- (5) SUMMARY OF CLAIMED SUBJECT MATTER**
- (6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**
- (7) GROUPING OF CLAIMS**
- (8) ARGUMENT**
  - (i) Rejection Under 35 U.S.C. § 112, first paragraph**
  - (ii) Rejection Under 35 U.S.C. § 112, second paragraph**
  - (iii) Rejections Under 35 U.S.C. § 102**
  - (iv) Rejections Under 35 U.S.C. § 103**
- (9) SUMMARY AND CONCLUSION**

Claims Appendix: Claims On Appeal

Appendix: References cited in Appeal Brief

Table of Contents